ADDAMEL N- chromic chloride, cuprous chloride, ferric chloride, manganese chloride, potassium iodide, sodium fluoride, sodium molybdate dihydrate, sodium selenite and zinc chloride injection, solution
Fresenius Kabi USA, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Addamel N

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of ADDAMEL N contains:

Active ingredients	Quantity
Chromic chloride 6 H_2O	5.33 µg
Copper chloride 2 H_2O	0.34 mg
Ferric chloride 6 H_2O	0.54 mg
Manganese chloride 4 H_2O	99.0 µg
Potassium iodide	16.6 µg
Sodium fluoride	0.21 mg
Sodium molybdate 2 H_2O	4.85 µg
Sodium selenite anhydrous	6.90 µg
Zinc chloride	1.36 mg

The active ingredients in 1 ml of ADDAMEL N correspond to:

Cr	0.02	µmol
Cu	2	µmol
Fe	2	µmol
Mn	0.5	µmol
I	0.1	µmol
F	5	µmol
Mo	0.02	µmol
Se	0.04	µmol
Zn	10	µmol

The content of sodium and potassium correspond to

Sodium	118 µg	5.12 µmol
Potassium	3.9 µg	0.1 µmol

PRODUCT PROPERTIES

- Osmolality: approx. 3100 mosm/kg water
- pH: 2.2

2. PHARMACEUTICAL FORM

Concentrate for solution for infusion

3. CLINICAL PARTICULARS

3.1 Therapeutic indications

ADDAMEL N is indicated in patients as a supplement in intravenous nutrition to meet basal to moderately increased requirements of trace elements.

3.2 Posology and method of administration

ADDAMEL N must not be given undiluted.

The recommended daily dosage of ADDAMEL N in adult patients with basal to moderately increased requirements is 10 ml (one ampoule).

For children weighing 15 kg or more, the recommended dosage is 0.1 ml ADDAMEL N/kg body weight/day.

3.3 Contraindications

Total biliary obstruction.

3.4 Special warnings and special precautions for use

ADDAMEL N should be used with caution in patients with impaired biliary and/or renal function in whom the excretion of trace elements may be significantly decreased.

ADDAMEL N should also be used with caution in patients with biochemical or clinical evidence of liver dysfunction (especially cholestasis).

If the treatment is continued for more than 4 weeks, checking of manganese levels is required.

ADDAMEL N must not be given undiluted.

3.5 Interaction with other medicaments and other forms of interaction

No interactions with other drugs have been observed.

3.6 Pregnancy and lactation

Animal reproduction studies or clinical investigations during pregnancy have not been carried out with ADDAMEL N. However, the requirements of trace elements in a pregnant woman are slightly

increased compared to non-pregnant women.

No adverse events are to be expected when ADDAMEL N is administered during pregnancy.

3.7 Effects on ability to drive and use machines

No effects on the ability to drive and use machines are to be expected.

3.8 Undesirable effects

No adverse effects related to the trace elements in ADDAMEL N have been reported.

Superficial thrombophlebitis has been observed when glucose containing ADDAMEL N was given. However, it is not possible to deduce whether this reaction is attributable to the infused trace elements

or not.

Allergic reactions to iodine may occur following topical application. No adverse reactions are known to occur as a consequence of using the recommended intravenous iodide dosage levels.

3.9 Overdose

In patients with impaired renal or biliary function, there is an increased risk for accumulation of trace elements.

In case of a chronic overload of iron there is a risk of haemosiderosis, which in severe and rare cases can be treated by venesection.

4. PHARMACOLOGICAL PROPERTIES

4.1 Pharmacodynamic properties

ADDAMEL N is a mixture of trace elements in amounts normally absorbed from the oral diet and should have no pharmacodynamic effect besides maintaining or repleting the nutritional status.

4.2 Pharmacokinetic properties

When infused intravenously, the trace elements in ADDAMEL N are handled in a similar way to trace elements from an oral diet. Individual trace elements will be taken up by tissues to different extents,

depending on the requirements within each tissue to maintain or restore the concentration of each element for the metabolic requirements of that tissue.

Copper and manganese are normally excreted via the bile, whereas selenium, zinc and chromium (especially in patients receiving intravenous nutrition) are mainly excreted via the urine.

The main route of molybdenum excretion is the urine, although small amounts are excreted in the bile.

Iron is eliminated in small amounts by superficial loss and desquamation of gut cells. Premenopausal women can lose 30-150 mg of iron in the monthly blood loss. Iron excretion follows all kinds of

bleedings.

4.3 Preclinical safety data

The safety evaluation is based mainly on clinical experience and documentation.

5. PHARMACEUTICAL PARTICULARS

5.1 List of excipients

Other ingredients	Quantity	Reference to standards
Xylitol	300 mg	Ph. Eur. + USP
Hydrochloric acid 1 M	to pH 2.2	Ph. Eur.
Water for injections	to 1 ml	Ph. Eur.

5.2 Incompatibilities

ADDAMEL N may only be added to or mixed with other medicinal products for which compatibility has been documented. See 5.6.

5.3 Shelf life

24 months

5.4 Special precautions for storage

Store below 25°C. Do not freeze.

5.5 Nature and contents of container

Ampoule, polypropylene

Pack size: 20 x 10 ml

5.6 Instructions for use/handling

ADDAMEL N must not be given undiluted.

COMPATIBILITY

Additions should be made aseptically.

Up to 20 ml ADDAMEL N can be added to 1000 ml Vamin Glucose, Vamin 14 Electrolyte Free, Vamin 18 Electrolyte Free and glucose solutions 50 mg/ml-500 mg/ml.

STABILITY

When additions are made to an infusion solution, the infusion should be completed within 24 hours from preparation to prevent microbiological contamination. The left over contents of opened

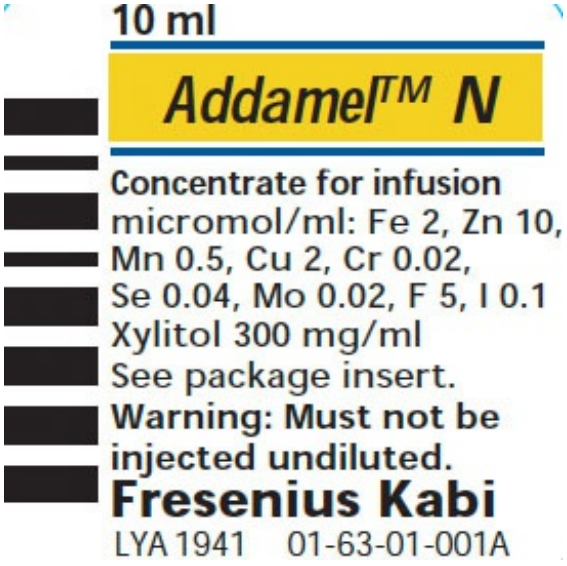
bottles/vials/ampoules should be discarded and not kept for later use.

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - Addamel™ N 10 mL Ampule Label

10 ml

Addamel™ N

Concentrate for infusion

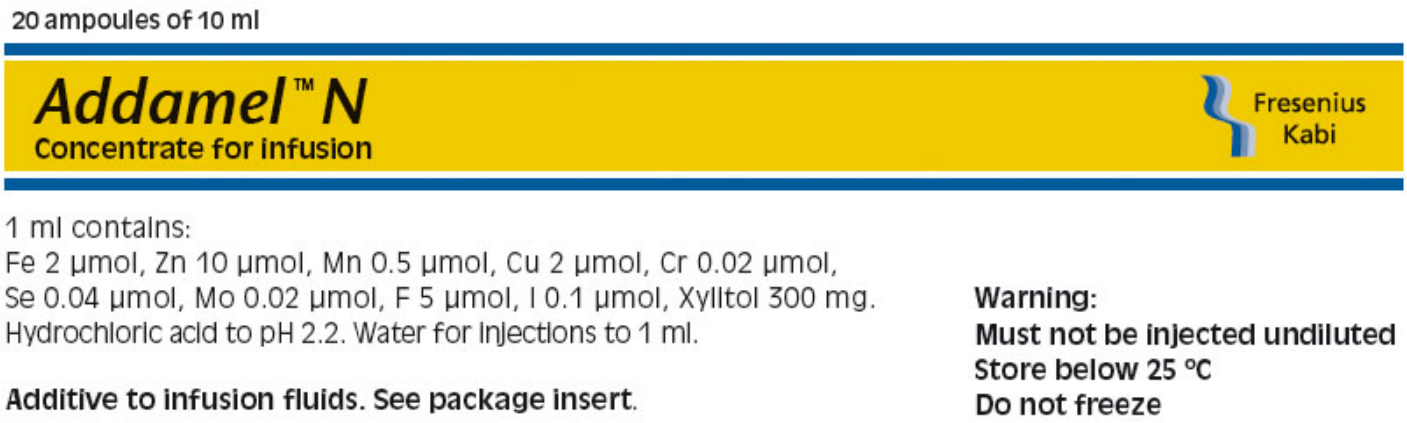


PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - Addamel™ N 10 mL Carton Panel

20 ampoules of 20 ml

Addamel™ N

Concentrate for infusion



ADDAMEL N

chromium, copper, iron, manganese, iodine, fluorine, molybdenum, selenium, and zinc injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63323-143
Route of Administration	INTRAVENOUS	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHROMIC CHLORIDE (UNII: KB1PCR9DMW) (CHROMIC CATION - UNII:X1N4508KF1)	CHROMIC CATION	1 ug in 1 mL
CUPROUS CHLORIDE (UNII: C955P95064) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	0.13 mg in 1 mL
FERRIC CHLORIDE (UNII: U38V3ZVV3V) (FERRIC CATION - UNII:91O4LML611)	FERRIC CATION	0.11 mg in 1 mL
MANGANESE CHLORIDE (UNII: QQE170PANO) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE CATION (2+)	0.027 mg in 1 mL
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	0.013 mg in 1 mL
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.095 mg in 1 mL
SODIUM MOLYBDATE DIHYDRATE (UNII: 8F2SXI1704) (MOLYBDATE ION - UNII:O0L10E6352)	MOLYBDATE ION	1.9 ug in 1 mL
SODIUM SELENITE (UNII: HIW548RQ3W) (SELENITE ION - UNII:KXO0259XJ1)	SELENITE ION	3.2 ug in 1 mL
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.65 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM (UNII: 9NEZ333N27)	5.12 umol in 1 mL
POTASSIUM (UNII: RWP5GA015D)	0.1 umol in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

XYLITOL (UNII: VCQ006KQ1E)	300 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63323-143-97	20 in 1 CARTON		
1		10 mL in 1 AMPULE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		05/07/2013	

Labeler - Fresenius Kabi USA, LLC (608775388)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi Norge AS		731170932	MANUFACTURE(63323-143)

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